

**Appl. No.** : **10/087,549**  
**Filed** : **February 28, 2002**

### **REMARKS**

Claims 1-15 are currently pending in the instant application. Claims 1, 7, 9 and 11 are currently presented for examination. Claims 1, 7, 9 and 11 are currently amended. Claims 2-6, 8, 10 and 12-15 have been withdrawn without prejudice or disclaimer.

Claims 1, 7, 9 and 11 have been amended. Support for the amendments of Claims 1, 7, 9 and 11 can be found at page 30, line 33, page 51, lines 6-22, page 56, lines 20-29, Figures 33A, 35 and 37 and elsewhere throughout the specification. Accordingly, no new matter has been added to the instant application.

#### Rejection of Claims 1, 7, 9 and 11 Under 35 U.S.C. § 103(a)

The Examiner rejects Claims 1, 7, 9 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Worthington et al (WO 00/26677, published 11 May 2000) in view of Collins et al (U.S. Patent No. 5,750,338, issued 12 May 1998). In particular, the Examiner alleges that Worthington et al. teach a method comprising the steps of preparing a test sample having a target DNA, preparing reporter beads having signal DNA which is complementary to the target, preparing capture DNA complementary to the target DNA and having an anchor agent, blocking the beads with a blocking agent, depositing the beads and test sample into a mixing chamber of an optical bio-disc, rotating the bio-disc allowing the beads to move into the target zone having an anchor agent for the capture agent, removing non-complexed beads and detecting bead complexes to determine the presence of the target DNA. The Examiner further asserts that Collins et al. teach pretreatment of beads to block non-specific binding sites. The Examiner then concludes that although Worthington et al. do not specifically teach the use of pre-treated capture beads to form dual-bead complexes, it would have been obvious to one of ordinary skill in the art to modify the sandwich hybridization of Worthington et al. by attaching a bead to both probes to thereby provide a larger and more visible target-probe complex.

Applicants respectfully disagree and maintain that Claims 1, 7, 9 and 11 are non-obvious in view of the combination of Worthington et al. and Collins et al. However, solely in order to expedite the allowance of the instant application, Applicants have amended Claims 1, 7, 9 and 11 to recite the limitation that the dual bead complex is isolated by "subjecting the test sample to a magnetic field" while the beads are on an optical bio-disc. Applicants respectfully submit that

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amended Claims 1, 7, 9 and 11 are allowable because neither Worthington et al. nor Collins et al. describe the step of isolating a dual bead complex by subjecting a test sample to a magnetic field while the beads are on an optical bio-disc. As such, the combined references fail to teach every element of the claims.

Applicants further submit that, contrary to Examiner's assertions on page 3 of the instant Office Action, Claims 1, 7, 9 and 11 are not obvious over Worthington et al. in view of Collins et al. because there is no motivation to use two beads. Worthington et al. describe detection of single-bead complexes and teach that the disclosed method "permitted ready discrimination between signal and background" and that the approach is "remarkably robust." (page 67, lines 15-20). Thus, one of ordinary skill in the art would not be motivated to modify the sandwich hybridization of Worthington et al. by attaching a bead to both probes to thereby provide a larger and more visible target-probe complex.

For at least the reasons set forth above, Applicants respectfully submit that Claims 1, 7, 9 and 11 are not obvious and request that the Examiner withdraw the rejection of Claims 1, 7, 9 and 11 under 35 U.S.C. § 103(a).

Rejection of Claims 1, 7, 9 and 11 Under 35 U.S.C. § 103(a)

The Examiner rejects Claims 1, 7, 9 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Oprandy (U.S. Patent No. 5,679,519, issued 21 October 1997) in view of Collins et al. (U.S. Patent No. 5,750,338, issued 12 May 1998) and Virtanen (WO 98/38510, published 3 September 1998). In particular, the Examiner alleges that Oprandy teaches a method of preparing a test sample having target DNA or RNA, preparing reporter beads having signal DNA which is complementary to the target, preparing capture DNA complementary to the target DNA and having an anchor agent, depositing the beads and test sample into a mixing chamber, allowing the beads to move into the target zone having an anchor agent for the capture agent, and removing non-complexed beads. The Examiner acknowledges that Oprandy teaches neither pretreatment of beads nor optical bio-disc detection. However, the Examiner goes on to assert that Collins et al. teach pretreatment of beads to block non-specific binding sites and that Virtanen teaches an optical bio-disc. The Examiner then concludes that it would have been

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obvious to one of ordinary skill in the art to combine the disclosures of all these various references to derive the subject matter recited in Claims 1, 7, 9 and 11.

Applicants respectfully disagree and maintain that Claims 1, 7, 9 and 11 are non-obvious in view of the combination of Oprandy, Collins et al. and Virtanen. However, solely in order to expedite the allowance of the instant application, Applicants have amended Claims 1, 7, 9 and 11 to recite the limitation that the dual bead complex is isolated by "subjecting the test sample to a magnetic field" while the beads are on an optical bio-disc. Applicants respectfully submit that amended Claims 1, 7, 9 and 11 are allowable because none of the references describe the step of isolating a dual bead complex by subjecting a test sample to a magnetic field while the beads are on an optical bio-disc. Furthermore, although Oprandy allegedly shows isolation of a dual bead complex using an electrode, Applicants submit that Oprandy does not disclose on-disc isolation. Furthermore, neither Collins et al. nor Virtanen provide this missing step. Accordingly, the combination of references cited by the Examiner fails to teach every element of the claims.

For at least the reasons set forth above, Applicants respectfully submit that Claims 1, 7, 9 and 11 are not obvious and request that the Examiner withdraw the rejection of Claims 1, 7, 9 and 11 under 35 U.S.C. § 103(a).

#### Obviousness-Type Double Patenting Rejection

The Examiner provisionally rejects Claims 1, 7, 9 and 11 of the instant application over Claims 1-28 of co-pending Application No. 09/997,741 under the judicially created doctrine of obviousness-type double patenting. In particular, the Examiner asserts that Claims 1-28 in co-pending Application No. 09/997,741 are directed to the same subject matter and fall entirely within the scope of the pending claims in the instant application.

Applicants do not concede that the claims in either application are obvious over one another. Applicants note that no claims have been issued in this case or in co-pending Application No. 09/997,741. The language of pending claims in one or both applications may change before issuance of any claim. As such, whether a terminal disclaimer is necessary cannot be determined until the issuance of at least one set of claims. If claims in Application No. 09/997,741 issue before the claims of the instant application, then a terminal disclaimer would be considered to resolve any remaining conflict in the scope of both sets of claims.

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### CONCLUSION

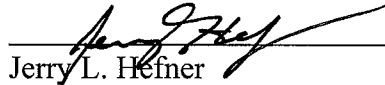
Applicants believe that all outstanding issues in this case have been resolved and that the present claims are in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact the undersigned at the telephone number provided below in order to expedite the resolution of such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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